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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,182	01/18/2002	Pier Giuseppe Pelicci	Mewburn	6367

110 7590 02/23/2007

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EXAMINER	
WAX, ROBERT A	
ART UNIT	PAPER NUMBER
1656	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	02/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/937,182	PELICCI ET AL.	
	Examiner	Art Unit	
	Robert A. Wax	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38 and 42-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38 and 42-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Introduction

1. Examiner has carefully considered the arguments presented with regard to the holding of lack of unity of invention of record. Examiner carefully reconsidered the reasons for holding lack of unity and realized that the explanation was not in accordance with PCT Rule 13.2, as argued by Applicants' attorney. Examiner also carefully reread the claims and noticed that some method steps were missing and some of the claims are worded awkwardly. The result is that the holding of lack of unity is revised herein and modified somewhat from the original. Examiner apologizes for any inconvenience but still feels that a holding of lack of unity is necessary.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, drawn to a product, DNA encoding $p66^{shc}$ with altered serine residues, vector and host cell containing it and the polypeptide encoded thereby and a method of making the protein.

Group II, claims 9-11, drawn to a method of modulating resistance in cells to oxidative stress comprising contacting said cell with an agent capable of modulating $p66^{shc}$ gene expression.

Group III, claim(s) 12-21, drawn to a method of increasing resistance in cells to oxidative stress comprising disrupting the $p66^{shc}$ signaling pathway. See also the new election of species requirement for this group below.

Group IV, claim(s) 22-27, drawn to a method for increasing resistance in cells to oxidative stress comprising administration of an effective amount of an agent which disrupts p66shc or a step in the $p66^{shc}$ signaling pathway. See also the new election of species requirement for this group below.

Group V, claim(s) 28-31, drawn to a method of increasing resistance to tumor formation comprising the step of increasing the expression of $p66^{shc}$.

Group VI, claim(s) 32-35, drawn to a method of screening for compounds capable of modulating resistance in cells to oxidative stress by modulating a $p66^{shc}$ signaling pathway.

Group VII, claim(s) 36-38, drawn to a method of reducing intracellular levels of reactive oxygen species in a cell by contacting with an agent capable of inhibiting the expression

or activity of $p66^{shc}$. See also the new election of species requirement for this group below.

Group VIII, claim 42, drawn to a method of determining the presence or absence of an unaltered $p66^{shc}$ nucleic acid by contacting with a specifically hybridizing nucleic acid.

Group IX, claim 43, drawn to a method of determining the presence or absence of an unaltered $p66^{shc}$ nucleic acid by contacting with an antibody-binding domain.

Group X, claim 44, drawn to an expression system comprising a nucleic acid vector having an unaltered $p66^{shc}$ coding sequence.

3. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The nucleic acid recited in claim 1 does not appear to be known in the prior art. However, not all of the groups of inventions require the nucleic acid encoding $p665^{shc}$ with mutated or missing serine residues. The only other claims which mention said nucleic acid are claims 14 and 15 but they are dependent claims drawn to a method of increasing resistance in cells to oxidative stress. If claims 14 and 15 were resubmitted as an independent group they would share unity of invention with Group I.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

For Group III:

Claims 13-16, drawn to a method of increasing resistance in cells to oxidative stress comprising disrupting the $p66^{shc}$ signaling pathway by affecting the susceptibility of $p66^{shc}$ to phosphorylation;

Claim 17, drawn to a method of increasing resistance in cells to oxidative stress comprising disrupting the $p66^{shc}$ signaling pathway by affecting the ability of a serine/threonine kinase, p38 or MAPK to phosphorylate $p66^{shc}$;

Claim 18, drawn to a method of increasing resistance in cells to oxidative stress comprising disrupting the $p66^{shc}$ signaling pathway by contacting the cell with an antibody binding domain capable of specifically binding to the p66shc polypeptide; and

Claims 19-21, drawn to a method of increasing resistance in cells to oxidative stress comprising disrupting the $p66^{shc}$ signaling pathway by disrupting $p66^{shc}$ gene expression.

For Group IV:

Claims 23-25, drawn to method for increasing resistance in cells to oxidative stress comprising administration of an effective amount of an agent which disrupts $p66^{shc}$ or a step in the $p66^{shc}$ signaling pathway where the agent is an antisense oligonucleotide;

Claim 26, drawn to method for increasing resistance in cells to oxidative stress comprising administration of an effective amount of an agent which disrupts p66shc or a step in the $p66^{shc}$ signaling pathway where the agent is an antibody binding domain capable of specifically binding to the $p66^{shc}$ polypeptide.

For Group VII:

Claim 37, drawn to a method of reducing intracellular levels of reactive oxygen species in a cell by contacting with an agent capable of inhibiting the expression of $p66^{shc}$ where the agent is a nucleic acid molecule and

Claim 38, drawn to a method of reducing intracellular levels of reactive oxygen species in a cell by contacting with an agent capable of inhibiting the activity of $p66^{shc}$ polypeptide where the agent is an antibody binding domain capable of specifically binding to the $p66^{shc}$ polypeptide.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Group III: each species represents a different, mutually exclusive active step which, even though they will all result in the disruption of the signaling pathway of $p66^{shc}$, utilize different, patentably distinct, agents; Group IV: each species represents a different, mutually exclusive active step which, even though they will all result in increasing cellular resistance to oxidative stress, utilize different, patentably distinct, agents and Group VII: each species represents a different, mutually exclusive active step which, even though

they will all result in reducing intracellular levels of reactive oxygen species in a cell, utilize different, patentably distinct, agents.

Applicant is required, if electing one of Groups III, IV or VII in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claims are generic: Group III: Claim 12; Group IV: Claims 22 and 27; Group VII: claim 36.

6. A telephone call was not made to request an oral election to the above restriction requirement in view of the complexity of the requirement.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of**

the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Objections

9. Claims 1, 2, 5-8, 12, 13, 17, 32 and 43 are objected to because of the following informalities: Claim 1 refers to the sequence of Figure 5, which is inappropriate. Reference should be made to SEQ ID No.: 1; claim 2 recites S120 but the amino acid at position 120 is Arg, perhaps S102 was intended; claim 12 contains the unintelligible phrase, "the pathway $p66^{shc}$ signaling pathway"; claims 13 and 17 recite, "effects" which should be "affects"; claim 32 appears incorrect in reciting, "a $p66^{shc}$ signaling pathway" since there is only one pathway (replacing "a" with "the" would correct this) and; claim 43 is incorrect since antibodies do not hybridize with nucleic acid (binding the protein was probably intended rather than hybridizing with the nucleic acid. Appropriate correction is required.

Sequence Rule Compliance

10. This application continues to fail to comply with the requirements of 37 CFR 1.821 through 1.825 because the coding region of SEQ ID No.: 1 is not depicted. Specifically, 37 CFR 1.822 (c)(3) states, in part, "The bases in the coding parts of a nucleotide sequence shall be listed as triplets (codons)." A correct sequence listing is required.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-

0623. The examiner can normally be reached on Monday through Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert A. Wax
Primary Examiner
Art Unit 1656

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